



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/747,742 | 12/29/2003 | Mark Tawa | TPI-2900C3XC2 | 2066 |
| 23557 7590 03/20/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950 | | | | |
| EXAMINER | | | | |
| ISSAC, ROY P | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1623 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/20/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/747,742

Applicant(s)

TAWA ET AL.

Examiner

ROY P. ISSAC

Art Unit

1623

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 26-29 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 26-29 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This application claims benefit of 60/486,713 07/11/2003 and claims benefit of 60/459,501 04/01/2003 and claims benefit of 60/456,608 03/21/2003 and claims benefit of 60/456,027 03/18/2003 and claims benefit of 60/441,335 01/21/2003 and claims benefit of 60/437,516 12/30/2002 and is a continuation in part of 10/601,092 06/20/2003 abandoned which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and is a CIP of PCT/US03/19574 06/20/2003 which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and said 10/601,092 06/20/2003 claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/428,515 11/22/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003. This application 10/747,742 is a CIP of PCT/US03/19574 06/20/2003 which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 This application 10/747,742 is a CIP of PCT/US03/41273 12/24/2003 which is a CIP of

Art Unit: 1623

10/601,092 06/20/2003 ABN which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and said PCT/US03/41273 12/24/2003 is a CIP of 10/660,202 09/11/2003 which is a CIP of PCT/US03/27772 09/04/2003 which is a CIP of 10/378,956 03/03/2003 which claims benefit of 60/360,768 03/01/2002 and said PCT/US03/27772 09/04/2003 claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003 and said 10/660,202 09/11/2003 is a CIP of 10/637,829 08/08/2003 which is a DIV of 10/295,995 11/18/2002 PAT 6,699,840 and said 10/295,995 is a CON of 10/232,589 09/03/2002 PAT 6,559,293 which claims benefit of 60/406,974 08/30/2002 and claims benefit of 60/380,288 05/15/2002 and claims benefit of 60/356,764 02/15/2002 and said 10/660,202 is a CIP of 10/449,307 05/30/2003 PAT 7,078,526 which claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/444,315 01/31/2003 and claims benefit of 60/439,282 01/10/2003 and claims benefit of 60/384,152 05/31/2002 and said 10/660,202 is a CIP of 10/601,092 06/20/2003 ABN and claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003.

This office action is in response to applicants' response to restriction requirement filed 12/12/07 wherein claims 8-25 and 30-31 have been cancelled and claims 7 and 26 have been amended and claim 32 have been newly submitted is acknowledged.

Election/Restrictions

Applicant's election with traverse of Group IV, claim 7 in part and claim 26, in the reply filed on 12/12/07 is acknowledged. The traversal is on the ground(s) that the two pending groups IV and V would not pose serious search burden for the examiner since they are both directed to sodium salts of celecoxib. This is found persuasive and the restriction requirement between groups IV and V is withdrawn. The pending claims, 7, 26-29 and 32 are examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 26-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talley et. al. (U.S. Patent No. 5,760,068; PTO-892) in view of Rubino et. al. (Int. J. Pharm. 65, 1990, 141-145; PTO-1449).

Talley discloses substituted benzene sulfonamides including celecoxib for the treatment of inflammation. Note that celecoxib is a widely used commercially available drug for pain.

Talley does not expressly disclose a propylene glycol solvate of celecoxib.

Rubino et. al. teaches that sodium salts of sulfonamides can be improved by crystallization in the presence of propylene glycol. (Abstract). Rubino notes that the crystal hydrate or solvate formation might play a role in the trends in the solubility data for the sodium salts. (Page 143, Column 2, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare sodium salts of celecoxib crystallized from propylene glycol solvates since celecoxib is a well known sulfonamide pharmaceutical used for the treatment of inflammation and Rubino et. al. discloses the preparation of propylene glycol sodium solvates of sulfonamides to improve solubilities.

Therefore, one of ordinary skill in the art would have reasonably expected that the preparation of celecoxib sodium salt glycol solvate would have substantially similar or better pharmaceutical effects.

Applicant's Examples in the specification (Example 7 of the published application) herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art. Example 7 provides no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no comparison to the same present i.e., testing data for the combination method herein in support of nonobviousness for the instant claimed invention over the prior art. Moreover, Example 7 merely describes the formation of a solvate of celecoxib. As discussed above, Rubino et. al. teaches that propylene glycol solvates of sodium salts of sulfonamides are expected to have higher solubility. As noted in MPEP (716.02), any differences

Art Unit: 1623

between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, one of ordinary skill in the art will view that a difference that is to the extent that is really is unexpected is absent.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy P. Issac
Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623